

### **REMARKS**

The present invention relates to a magnetic substance-encapsulated particle.

#### **I. The Office Action**

In the Office Action dated May 29, 2008, claims 2 - 8 and 10 - 28 were all the claims pending in the application, and claims 2 - 8, 10 - 17, 27, and 28 were rejected. The Examiner recognized Applicant's election without traverse of Group 1, claims 1 - 17, and claims 18 - 26 were withdrawn. Also, the Examiner acknowledged and entered Applicant's amendments and remarks filed February 14, 2008.

Claims 2 - 8, 10 - 14, and 27 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kasai et al, (U.S. Patent No. 5,814,687) (hereafter "Kasai") in view of Wang et al, (U.S. Patent No. 5,283,079) (hereafter "Wang"). Claims 15 - 17 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kasai in view of Wang, further in view of Noetzel et al, (U.S. Patent No. 4,568,706) (hereafter "Noetzel"). Claim 28 was rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Kasai in view of Wang, in further view of Ko et al, (JP 2003-012709) (hereafter "Ko").

#### **II. Amendment**

Applicant has amended claim 2 as indicated above to more specifically define Applicant's invention. Support for this amendment is found, for example, at page 13, lines 33 - 35 of the present application. Also, claim 2 is amended to correct for proper antecedent basis.

### **III. Response to Rejection of Claims 2 - 8, 10 - 14, and 27 under 35 U.S.C. § 103(a)**

Applicant respectfully traverses. Applicant respectfully submits that for the reasons explained below, the two references relied upon for this rejection under 35 U.S.C. § 103(a) do not provide sufficient basis for a person of ordinary skill in the art to derive the presently claimed invention. Accordingly, for the reasons explained further in detail below, it is respectfully submitted that this rejection under 35 U.S.C. § 103(a) should now be withdrawn.

As recited in present claim 2, in relevant part: “an absolute deviation of a component ratio between a carbon element composing the organic polymer material and a metal element composing the magnetic substance is 0.27 or less.”

This feature of the claimed invention has proven critical to achieving remarkable, unexpected results in an immunoassay. In preparation for the experiment it was shown that Examples 15 - 18 had an absolute deviation which measured 0.27 or less (see page 44, Table 6 of the specification). In particular, the absolute deviation of Example 17 measured at a ratio of 0.2504. The magnetic substance-encapsulated particles of Example 17 were transformed into Example 19, as described. See page 37, lines 27 - 29 of the specification. Example 19 was further transformed into Example 21 for testing in an immunoassay. See page 39, lines 11 - 12 of the specification. Examples of the claimed invention, including Example 21, exhibited surprisingly strong immunoassay results. See page 47, lines 18 - 23. In particular, the coloring of Examples with an absolute deviation of 0.27 or below, including Example 21, was found to depend on the concentration of hCG present on the Example, such that portions tested without specimen exhibited an hCG concentration of 0 mUI/ml.

A comparative example having an absolute deviation above 0.27 were found to yield poor results in immunoassays (see, for example, page 44, Table 6). In contrast to the above, a

comparative example was prepared which had an absolute deviation above 0.27. The magnetic substance-encapsulated particles of Comparative Example 1 had an absolute deviation ratio of 0.3451. Comparative Example 1 was transformed into Comparative Example 4. See page 40, lines 18 - 20 of the specification. Comparative Example 4, exhibited coloring in every test, even on portions where there was no material to detect. See page 47, lines 23-35 the specification. These results indicate a lack of specificity in the immunoassay.

In conclusion, these experimental results indicate that using magnetic substance-encapsulated particles in an immunoassay with an absolute deviation of component ratio above 0.27 leads to non-specific reactions, such that those materials are not inferior for use in an immunoassay. Conversely, these results also indicate that using magnetic substance-encapsulated particles in an immunoassay with an absolute deviation of component ratio of 0.27 or less is suitable for use in immunoassays. Therefore, the absolute deviation recited in claim 2, namely "0.27 or less," is an important aspect of the presently claimed invention and would not be obvious to one of ordinary skill in the art.

U.S. Patent No. 5,814,687 (Kasai)

The Office Action cited Kasai as disclosing magnetic polymer particles that are configured by incorporating a magnetic substance into an organic polymer material, where the magnetic polymer particle is characterized by a number average particle diameter of magnetic polymer particles which is generally 0.02 - 10  $\mu\text{m}$ M. Kasai is also cited as disclosing that the magnetic substance is homogeneously dispersed throughout the center of the magnetic polymer particles.

However, Kasai does not teach or suggest the relevant feature as defined in pending claim 2, where the absolute deviation of a component ratio between a carbon element composing the organic polymer material and a metal element composing the magnetic substance is 0.27 or less. Kasai is silent on the issue of absolute deviation and its effects on the specificity of immunoassays.

Accordingly, it is clear that Kasai does not affect the unobviousness of claims 2 - 8, 10 - 14, and 27.

U.S. Patent No. 5,814,687 (Wang)

The Office Action cited Wang as disclosing the use of magnetic particles having uniform size distribution and magnetic content useful in immunoassays and for a wide variety of biomedical applications. Wang also discloses that the magnetic particles can be optimized in terms of magnetic substance content for a wide variety of biomedical applications.

However, Wang does not teach or suggest that the absolute deviation of a component ratio, between a carbon element composing the organic polymer material and a metal element composing the magnetic substance, is 0.27 or less or that this ratio is critical to immunoassay specificity. Although Wang suggests that magnetic particles can be optimized in terms of size, surface area, metal oxide content, and surface characteristics, Wang is silent about the optimization of the absolute deviation of the ratio of carbon to magnetic substance. See column 5, lines 65 - 68 of Wang.

Accordingly, Wang adds nothing to Kasai that would render claims 2 - 8, 10 - 14, and 27 obvious under 35 U.S.C. § 103(a).

**IV. Response to Rejection of Claims 15 - 17 and 28 under 35 U.S.C. § 103(a)**

Claims 15 - 17 and 28 each incorporate the terms of claim 2, so in view of the above, Applicant respectfully submits that these rejections are rendered moot.

**V. Rejoinder Requested**

Applicant again respectfully submits that the method of claims 18 - 22 are commensurate with product claim 2 and, therefore are appropriate for rejoinder upon a determination of patentability of the product claims. Therefore, Applicant submits that rejoinder is proper.

**Conclusion**

In view of the above, reconsideration and allowance of claims 2 - 8, 10 - 22, and 27 - 28 of this application are now believed to be in order, and such actions are hereby solicited.

If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned attorney at the local Washington, D.C., telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,

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